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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,863	05/01/2001	Philip Goelet	13020-2-D1	5388

7590 03/27/2007

Kalow & Springut LLP
488 Madison Avenue, 19th Floor
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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/846,863	GOELET ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

2. As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino

> acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. In the present case it is noted that the first paragraph pf the specification is not directed to cross-reference to related application. While an amendment to the specification was made on 06 May 2005, the placement of this paragraph has not been changed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 32-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue.". See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not

> 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary

The quantity of experimentation is great- on the order of several man-years with little if any reasonable expectation of ever being fully enabled. Indeed, in the 14 years post the claim for priority, the full enablement still ahs not been achieved

The amount of direction or guidance presented,

The amount of guidance provided is limited.

The presence or absence of working examples

The specification has been found to provide the following examples:

- Example 1, "Discovery of Equine Polymorphisms," pp. 45-47;
- Example 2, "Characterization of Equine Polymorphisms," pp. 47-50;
- Example 3, "Allelic Frequency Analysis of Equine Polymorphisms in Small Population Studies" (50-60 animals), pp. 50-54;
- Example 5, "Parentage Testing" (equine), pp. 55;
- Example 5, "Identity testing," pp. 56-58; and

- Example 6, "Analysis of a Human SNP," pp. 58-62.

Of the six examples provided, none disclose how one would test and evaluate the myriad "species of interest," much less identify said single nucleotide polymorphisms in a simultaneous manner any number of individuals (claims 32, 36-39, and 43-45), or when testing the "smaller" value of 10,000 individuals (limitation of claims 35 and 42).

While the specification does present several examples, such are directed to the analysis of but equine and human DNA and then primarily to the analysis of equine DNA as it relates to parentage analysis (Example 4). Said six examples do not provide an adequate written description of the claimed method whereby one would be able to determine any and all single nucleotide polymorphisms in any and all species of mammals. As presently worded, the claimed method fairly encompasses performing the identification when but one strand is sequenced and/or is present in but only one haploid example. Page 47 of the disclosure, however, teaches, "Differences were concluded to be a DNA polymorphism only if the data was available for both strands, and/or present in more than one haploid example among the five horses tested." The specification does not provide an adequate written description of how to practice the full scope of the invention where but one strand is analyzed and/or where the frequency of the polymorphism is less frequent than 1 in 5, be the species human, equine, or non-human primate, dogs, cats, cattle, or sheep, as is recited in claim 48 and 53.

Example 1 clearly teaches that equine polymorphisms were identified in the breed of horses known as thoroughbred. The specification has not provided any teaching that polymorphisms found in one breed is also found in another breed, especially when the phenotype of the breeds is highly divergent, which in turn fairly suggests that the genetic makeup of the two

equines is highly dissimilar, e.g., the Lithuanian Heavy Draft and the Noma, where the Lithuanian Heavy Draft was first recognized in 1964, with the Noma originating in the seventeenth century. While both are horses, the existence of one for centuries and the non-existence of the other until a few decades ago speaks to their genetic diversity. The specification fails to provide an adequate written description of how one would recognize and use single nucleotide polymorphisms (SNPs) in one breed to in turn recognize an individual in another breed, much less determine paternity.

The nature of the invention and breadth of claims

In accordance with claims 32-38 and 46-52, one is identifying the presence of single nucleotide polymorphisms (SNP) in any mammal. The SNP does not have to be associated with any specific trait, much less have any specific, substantial, or credible utility. The specification is essentially silent s to how one would be able to identify useful SNPs from those that are not, and to then be able to use them in a method that meets the utility requirements.

Claims 39-45 and 53-55 are drawn to a method of determining allelic frequency at a SNP site. Claims 56-58 are drawn to determining parentage in equine, with claims 59-61 being drawn to determining parentage in any mammal.

The state of the prior art

Nickerson et al., teach in their 2001 article:

> One problem, common to all methods of SNP and mutation detection, is that experimental conditions required for detection of DNA sequence variants depend on the specific DNA sequence to be analyzed. Although algorithms and other calculations have been developed to predict the experimental conditions required to detect DNA sequence variation in a specific DNA sequence, these algorithms do not always provide reliable information and experimental conditions for SNP and mutation detection must be devised empirically. Determination of experimental conditions for detection of DNA sequence variation is difficult when samples containing only wild type sequence are available.

As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

In view of art-recognized unpredictable nature of the art, greater level of disclosure is required for enablement.

The predictability or unpredictability of the art

As seen above, the predictability of the art is low, as the conditions used to detect the presence of SNP must be devised empirically. The specification provides at best one set of conditions, and those were for a specific breed of horses. There is no showing that the same conditions work for any other breed, much les other species. In view of the 2001 article cited above, there is no reason to expect that one condition would work for sample from another individual, or for a sample from a different tissue/source in the same individual.

7. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Response to argument

8. At page 12 of the response received 04 January 2007, hereinafter the response, applicant's representative makes statements as to what one of skill in the art would have interpreted the claims to encompass. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

9. At page 13, bridging to page 14, said representative asserts that impermissible hindsight was used in interpreting the claims as simultaneous sequencing was not invented until about 2002. "which is well after the filing date of the present application."

10. In view of the agreement that the claims do encompass such an embodiment, and that the technology was not developed until about 9 years post filing of the priority date of the instant application, it is not possible for applicant to have enabled such. As for the use of hindsight to interpret claim scope, attention is directed to MPEP 2111:

> **2111 [R-5] Claim Interpretation; Broadest Reasonable Interpretation**
>
> **CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE**
>
> **INTERPRETATION**
>
> 415 F.3d at 1316, 75 USPQ2d at 1329. See also< In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the

> claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified.

11. At page 14 of the response argument is presented that starting material is provided, and that the specification is fully enabled.

The above argument has not been found persuasive as the specification does not provide starting materials for an adequate number of species so as to reasonably suggest that applicant had possession of the claimed genus. It is noted with particular that the specification only provides equine SNPs, and a method for establishing parentage in equines. The methods, however, are not limited to equines. As seen in claim 53, for example, the "mammal is selected from the group consisting of human, non-human primates, dogs, cats, cattle, sheep, and horses." Indeed, claims 32-47 and 61 are not limited to any species but rather, fairly encompass any and all manner of mammals. The specification has not presented any showing that equine SNPs are useful in identifying he source, condition, or parentage of any other species and as such, the showing of various SNPs in equine has no effect on one being able to analyze non-equine mammalian samples. In support of this position attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.
>
> ***

> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

12. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.

17. Erlich et al., Figure 1, Table 1, Figure 2 and corresponding legend and Figure 3, teach a method of identifying single nucleotide polymorphic sites in a genome of interest. As seen in the chart/table at pages 38-39, at least 18 different DNA sequences were evaluated with specific SNPs explicitly identified through comparison with other sequences. Such a showing meets a limitation of claim 33-35 and 40-42.

18. As set forth in the title and abstract, the method comprises the performance of PCR. Accordingly, a limitation of claims 38 and 45 has been met.

19. Erlich et al., page 34, teaches analysis of a human chromosome six. Such a showing meets a limitation of claims 48, 51, 53, 54, and 59.

20. To the degree that claims recite limitations as to the specific size of a test grouping, or of the fragment size or detection means, such limitations are not deemed to rise to the level of a patentable distinction but rather, are the result of routine optimization. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however,

changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136.

21. For the above reasons, and in the absence of convincing evidence to the contrary, claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.

22. Claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

23. See above for the basis of the rejection as it pertains to the disclosure of Erlich et al.

24. Fey et al., teach using DNA polymorphisms in identifying parentage, and that the method can be applied to humans, and more broadly to animals and plants (page 821), and the species of each. Fey et al., page 818, teaches using polymorphisms associated with HLA.

25. Accordingly, and in the absence of convincing evidence to the contrary, claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

26. In view of the prior art teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the disclosures of Fey et al., with that of Erlich et al., as the application of DNA polymorphisms would have allowed the ordinary artisan to apply the technology to screening of relatedness between species and well as between members of a species, including the identification of parentage. In view of the detailed description provided, and the desire of such technology in the work place, the ordinary artisan would have been highly motivated and would have had a most reasonable expectation of success.

Response to arguments

At page 15, bridging to page 16 of the response argument is presented that the prior art does not teach SNPs, but rather, "polymorphic regions containing at least 2 or 3 nucleotide variations." This argument ahs been fully considered and has not bee found persuasive, for while Erlich et al., does teach of multi-nucleotide variations, they also teach explicitly of SNPs. For convenience, portions of the chart found at pages 38 and 39 (Figure 3) are reproduced below.

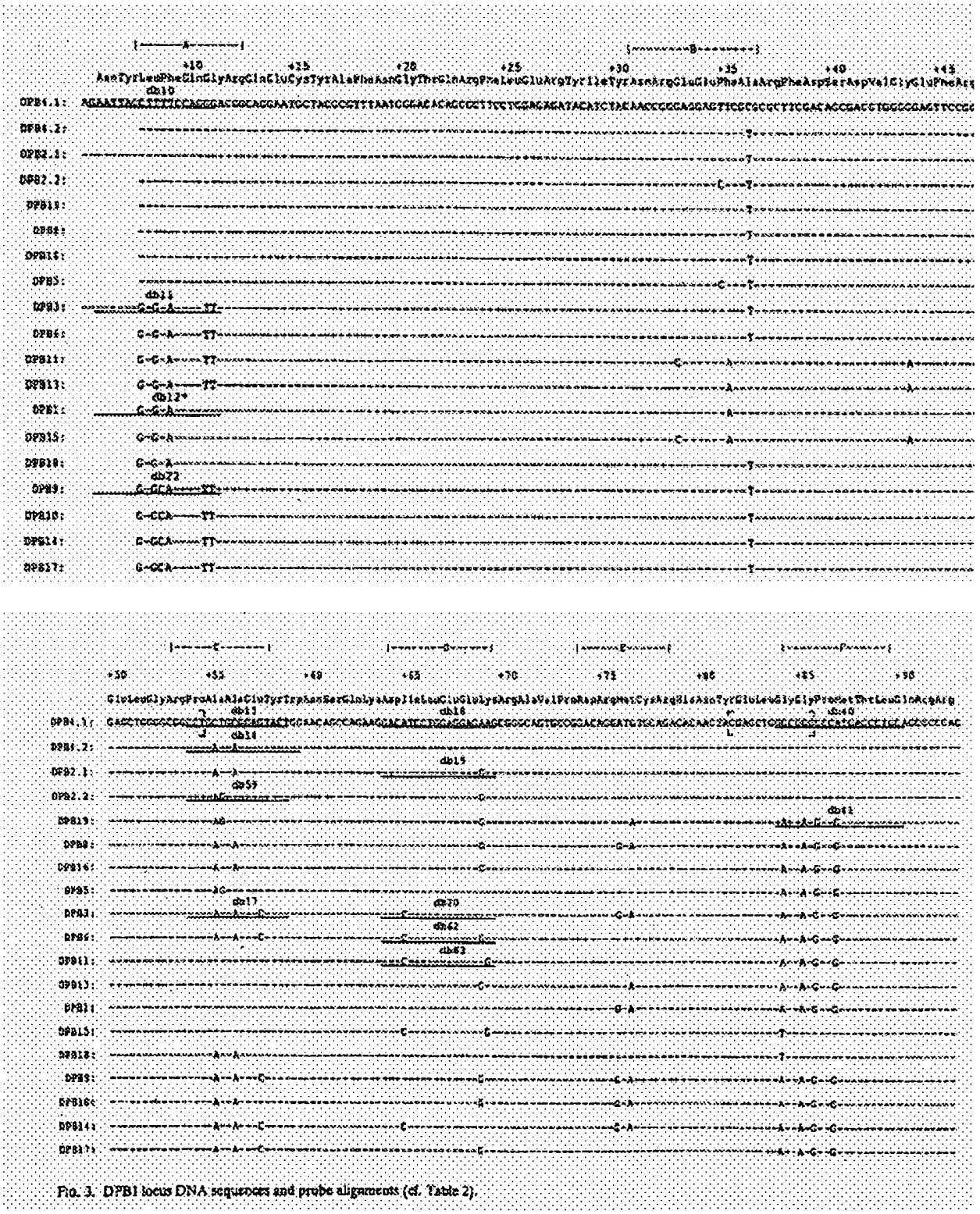


FIG. 3. DPB1 locus DNA sequences and probe alignments (cf. Table 2).

27. As is clearly seen above, there are a large number of SNPs explicitly identified, where a SNP is immediately flanked by a 3' and 5' invariant nucleotide sequence. Indeed, in looking at the first comparison sequence (DPB4.2), there are at least 3 SNPs present; and in DPB18 there are at least 7 SNPs identified.

28. At page 9 of the response argument is presented that Fey does not overcome the deficiencies of Erlich et al. This argument has been fully considered and has not been found persuasive for as shown above, Erlich et al., does teach the claimed limitations.

29. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

30. For the above reasons, and in the absence of convincing evidence to the contrary, claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al.; and claims 33-35, and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al., as applied to claims 32-36, 38-43, 45, 46, 48, 51, 53, 54, and 59 above, and further in view of Fey et al.

Conclusion

31. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

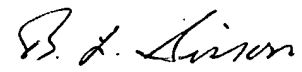
32. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS